NOV - 6 2000

K003296

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy J. Bickel
(219) 372-1761

Device(s): Biomet® SCK Knee System

Classification Name:
Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (CFR 888.3560)

Device Classification: Class II

Device Product Code: 87 JWH 888.3560

Intended Use:

- Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, and/or traumatic arthritis where one or more compartments are involved.
- Correction of varus, valgus, or posttraumatic deformity.
- Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure

This device is for use with bone cement

Device Description:

The Biomet® SCK Knee System has an open box femoral component with locked tibial bearing, that will utilize the Maximum Congruent Knee (K915132) tibial trays. All SCK implants are manufactured from the same materials as the Maximum Congruent Knee (K915132) implants

The tibial bearing has a high, wide post with a lip at the top. The sagittal tibial profile has a 'dished' surface that will interact with the distal radius of the femoral component. The tibial bearings are available in sizes 59, 63/67, 71/75, 79/83, and 87/91, with thickness ranging from 10mm thick to 24mm in 2mm increments. The SCK tibial bearing is composed of ArCOM® UHMWPE (ASTM F648).

The SCK femoral component is made from cast Cobalt Chrome alloy (ASTM F75). The femoral component has an open box structure with an outer width of inches. For stem attachment there is a boss angle of 6° located superiorly to the box. The SCK femoral components are available in five anatomical sizes, 60-80mm in five millimeter increments.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disease	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive wear
Tissue growth failure	Nerve damage	

Predicate Device(s):
Maximum Congruent Knee, K915132- Manufactured by Biomet, Inc. Warsaw, IN.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Tracy J. Bickel
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581

Re: K003296
Trade Name: Biomet SCK Knee System
Regulatory Class: II
Product Code: JWH
Dated: October 18, 2000
Received: October 20, 2000

Dear Ms. Bickel:

We have reviewed your Section 510(k) notification of intent to market the ~~device referenced~~ above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K00-3296
Device Name: **Biomet® SCK Knee System**
Indications for Use:

The Biomet® SCK Knee System is indicated for:

1) Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, and/or traumatic arthritis where one or more compartments are involved.
2) Correction of varus, valgus, or posttraumatic deformity.
3) Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is for use with bone cement

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K00 3296

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